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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/674,935	12/21/2000	Timothy Raymond Hirst	9274	8699

24126 7590 11/15/2006

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EXAMINER	
HINES, JANA A	

ART UNIT	PAPER NUMBER
1645	

DATE MAILED: 11/15/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Advisory Action Before the Filing of an Appeal Brief	**Application No.** 09/674,935	**Applicant(s)** HIRST ET AL.	
	Examiner Ja-Na Hines	**Art Unit** 1645	

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 16 October 2006 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☒ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:
   a) ☒ The period for reply expires 3 months from the mailing date of the final rejection.
   b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

   Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

NOTICE OF APPEAL

2. ☐ The Notice of Appeal was filed on _____. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

AMENDMENTS

3. ☒ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because
   (a) ☒ They raise new issues that would require further consideration and/or search (see NOTE below);
   (b) ☐ They raise the issue of new matter (see NOTE below);
   (c) ☒ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
   (d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

   NOTE: _____. (See 37 CFR 1.116 and 41.33(a)).
4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).
5. ☐ Applicant's reply has overcome the following rejection(s): _____.
6. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
7. ☒ For purposes of appeal, the proposed amendment(s): a) ☐ will not be entered, or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.
   The status of the claim(s) is (or will be) as follows:
   Claim(s) allowed: *None*.
   Claim(s) objected to: *None*.
   Claim(s) rejected: *38-53*.
   Claim(s) withdrawn from consideration: *None*.

AFFIDAVIT OR OTHER EVIDENCE

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).
9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing a good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).
10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

REQUEST FOR RECONSIDERATION/OTHER

11. ☐ The request for reconsideration has been considered but does NOT place the application in condition for allowance because: _____.
12. ☐ Note the attached Information Disclosure Statement(s). (PTO/SB/08) Paper No(s). _____
13. ☐ Other: _____.

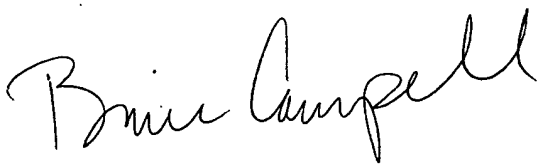
The proposed after final amendments will not be entered because they raise new issues that require further search and consideration. The new issues that drawn to the enhancement of a leukocyte mediated or immunoglobulin mediated immune response. This limitations was not previously recited by the claims and appears to narrow the scope of the claims. Furthermore, the proposed amendment does not place the application in better form for appeal. Therefore the after final amendment will not be enetered.

It is noted that applicants arguments are drawn to the proposed after final amendment which has not been entered, therefore applicants' arguments towards such are not relevant at this point in prosecution.

The rejection of claims 38-53 under 35 U.S.C. 112, second paragraph, is maintained. Applicants' assert that the term is commonly employed and that there is no absolute standard. However it is the examiner's position that the claims are indefinite because the claims do not refer to any type of comparison. The claims broadly recite enhanced immune response and are not limited to the levels of B and T cells, there is no disclosure of what the baseline level of an immune response should be which in-turn allows one to know when an enhanced level is reached. Thus the metes and bounds of the phrase cannot be ascertained and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention with respect to this enhanced level of an immune response.

The rejection of claims 38-39, 43-45 and 49 under 35 U.S.C. 102(b) as being anticipated by Williams et al., (WO 97/02045) is maintained for reasons already of record. The rejection was on the grounds that Williams et al., clearly teach a method for enhancing the level of an immune response to a vaccine against an infectious agent in a mammalian subject comprising administering to the subject an effective amount of the B subunit of E.coli heat labile enterotoxin (ExtB) wherein the EtxB is free from whole toxin and not linked to an antigen just as required by the instant claims.

The rejection of claims 38-53 under 35 U.S.C. 102(b) as being anticipated by Hazama et al., (Immunology, 1993) is maintained for reasons already of record. THe rejection is maintained on the grounds that Hazama et al., teach a method for enhancing the level of an immune response to a glycoprotein vaccine against a HSV-1 infectious agent in a mouse subject comprising administering to the subject an effective amount of the B subunit of E.coli heat labile enterotoxin (ExtB) as known as LTB wherein the EtxB or LTB is free from whole toxin and not linked to an antigen just as required by the instant claims.



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